

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE LITIGATION	)	
	)	CIVIL ACTION NO.
	)	01-12257-PBS

THE STATE OF FLORIDA

*ex rel.*,

VEN-A-CARE OF THE FLORIDA KEYS, INC., a Florida Corporation, by and through its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES,

Plaintiffs,

V.

ALPHARMA, INC.; ALPHARMA, USPD, INC., f/k/a  
BARRE-NATIONAL, INC.; BARRE PARENT  
CORPORATION; FAULDING, INC.; IVAX  
CORPORATION; IVAX PHARMACEUTICALS, INC.,  
f/k/a ZENITH-GOLDLINE PHARMACEUTICALS,  
INC.; MAYNE GROUP, LTD.; SANDOZ INC., f/k/a  
GENEVA PHARMACEUTICALS, INC.; NOVARTIS  
AG; AND PUREPAC PHARMACEUTICAL CO.,

Defendants.

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO**  
**PLAINTIFFS' MOTION FOR REMAND TO STATE CIRCUIT COURT**

## Introduction

Plaintiffs’ August 18, 2005 Motion for Remand should be denied. This lawsuit is one of dozens of pharmaceutical average wholesale price (“AWP”) actions that have been

pending since 2001. Many of those cases involve state law claims similar to those asserted by plaintiffs here. Beginning in 2002, the Judicial Panel on Multidistrict Litigation (JPML) has transferred more than thirty such cases, including other cases brought by other state Attorneys General involving state law claims similar to those asserted by plaintiffs here, to this Court for consolidated and coordinated pre-trial proceedings in federal court there. *See generally In re: Pharmaceutical Industry Average Wholesale Pricing Litigation*, MDL 1456 (D. Mass. 2002).

This case belongs in federal court because it requires resolution of real and substantial federal questions, which plaintiffs fail to acknowledge are at the heart of their claims. Plaintiffs deny that their claims for alleged overcharges for Medicaid covered drugs are properly removable because they are asserted under the Florida False Claims Act and Florida common law. However, plaintiffs do not dispute that these claims depend on interpretation of key terms such as AWP, “wholesale acquisition cost” (WAC) and “Federal Upper Limit” (FUL) that are employed in the federal Medicaid statute and regulations, thus raising substantial questions of federal law that give rise to federal jurisdiction. These specific terms are repeatedly identified as being crucial to plaintiffs’ claims. *See, e.g.*, Complaint ¶¶ 18-31. Plaintiffs’ reliance on these terms is most clearly shown when they outline the “Actionable Conduct of Defendants.” *See* Complaint pp. 13-16. For instance, plaintiffs assert that the defendants submitted “false, inflated prices and costs, including AWP’s and WACs, for specified pharmaceuticals . . . .” *Id.* ¶¶ 37, 38, 39.

Plaintiffs' allegations in this case present substantial federal questions that are properly before the Court. Plaintiffs' allegations that defendants submitted "false, inflated prices and costs, including AWP's and WAC's, for specified pharmaceuticals," if proven, will affect the "federal share" paid to Florida in the Medicaid program under the Social Security Act. *See* 42 U.S.C. § 1396b. The federal government's payment of the federal share under the Medicaid program to Florida must inevitably be a component of Florida's claims in this case. Although the federal payment is not referenced in the Complaint, a substantial federal question exists about what amount was properly paid by the federal government to plaintiffs based on the purported false, inflated prices and costs, including AWP's and WAC's. The methodology and determination of this amount is based on federal law. *See* 42 U.S.C. § 1396b(d)(2); *see also* 42 C.F.R. Part 447.

This Court is already involved in a (non-removed) Medicaid action filed by the Commonwealth of Massachusetts against some of the same defendants that were sued by Florida. *Commonwealth of Massachusetts v. Mylan Laboratories*, Civil Action No. 03-11865-PBS. Massachusetts seeks a monetary recovery based on what the Commonwealth alleges are inflated and false pricing of pharmaceutical products under the Commonwealth's Medicaid program. In addition, this Court has before it a similar action filed by the State of California, and Ven-A-Care of the Florida Keys, Inc., which is also a plaintiff/relator in the State of Florida's action. *State of California v. Abbott Laboratories*, Civil Action No. 03-11226-PBS.

Were there any doubt about whether this case belongs in federal court, that doubt was eliminated by a recent Supreme Court ruling. The Court refined the law on removal

in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfr.*, 125 S. Ct. 2363 (2005). *Grable* ruled that federal question jurisdiction “will lie over state-law claims that implicate significant federal issues” as a federal court should be able to hear claims “recognized under state law” when those state law claims “nonetheless turn on substantial questions of federal law . . . .” *Id.* at 2367. Federal jurisdiction is thus proper in those circumstances unless maintaining the case in federal court would disturb a “congressionally approved balance of federal and state responsibilities.” *Id.* at 2368.

### **Procedural History of This Litigation**

On April 6, 2005, plaintiffs filed (but did not serve) a Complaint styled *State of Florida v. Alharma, Inc.*, Nos. 03-CA1165A, 98-3032F (Fla. 2d Cir. Ct.) in the Court of the Second Judicial Circuit in and for Leon County, Florida.<sup>1</sup> Similar to other AWP actions, the Complaint alleges that the defendants misrepresented their respective AWP and WAC in connection with their reporting of their product pricing information to First DataBank, Inc., a consolidator and publisher of prescription drug pricing information. *See* Complaint ¶¶ 26-36. According to the Complaint, these alleged misrepresentations defrauded the Florida Medicaid program, causing it to pay provider claims in amounts far in excess of the prices and “costs generally or currently available in the marketplace.” *See* Complaint ¶ 30.

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<sup>1</sup> Not all of the named defendants have been served with process in this action. For those defendants who have not been served, their counsels’ identification below indicates their consent to the positions set forth in this Memorandum. Such consent is not a waiver of service of process nor of any right to contest the exercise of personal jurisdiction.

On July 20, 2005, defendants removed this action to the United States District Court for the Northern District of Florida, under 28 U.S.C. § 1331. On July 25, 2005, defendant Sandoz Inc. filed a notice of related action designating this action as a tag-along action related to those actions already transferred to the AWP MDL for consolidated and coordinated pretrial proceedings with the JPML.

On August 9, 2005, the JPML entered an Order noting that this case and others had been conditionally transferred to the JPML. Plaintiffs had until August 24, 2005, to object to that transfer. However, they filed no objection. On August 25, 2005, this case was transferred to this Court by the JPML. On September 1, 2005, this Court issued an order that the case be consolidated with Civil Action No. 01-12257-PBS.

Because plaintiffs' August 18, 2005 Motion for Remand had been filed in federal court in the Northern District of Florida, and defendants had not yet responded when this case was transferred to this Court, the parties agreed to a new briefing schedule.<sup>2</sup> On September 16, 2005, plaintiffs filed a timely Memorandum of Law In Support of Motion for Remand ("Plaintiffs' Memo."), to which defendants now respond.

### **The Multidistrict Litigation Proceedings**

In April 2002, the JPML transferred sixteen AWP cases to this Court for coordinated or consolidated pretrial proceedings because "[c]entralization of all actions . . . in the District of Massachusetts will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation [and] . . . avoid

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<sup>2</sup> That schedule was adopted by Magistrate Judge Bowler on October 4, 2005.

duplication of discovery, prevent inconsistent or repetitive pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary.” *In re: Immunex Corp.*

*Average Wholesale Price Litig.*, 201 F. Supp. 2d 1378, 1380 (J.P.M.L. 2002). Since April 2002, the JPML has transferred approximately fifty-nine additional AWP cases to this Court, many of which had been removed from state courts.

Since its original order in April 2002, the JPML has consistently transferred cases (referred to as “tag-along actions”) to the this Court. To date, the JPML has ordered the transfer of thirty-four cases, including a number of cases where plaintiffs objected and remand motions were pending.<sup>3</sup> Because plaintiffs did not object to the conditional

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<sup>3</sup> In light of *Grable*, in July 2005, eleven additional cases brought by seven states were removed to federal court, although most of those actions are still subject to possible remand. *See State of Alabama v. Abbott Laboratories, Inc., et al.*, Case No. 2:05cv-647-T, Notice of Removal (M.D. AL July 13, 2005); *State of Illinois v. Abbott Laboratories, Inc., et al.*, Case No. 05C 4056, Notice of Removal (N.D. Ill. July 13, 2005); *Commonwealth of Kentucky v. Alpharma, Inc., et al.*, Case No. 05 CV 47, Notice of Removal (E.D. Ky. July 13, 2005); *Commonwealth of Kentucky v. Abbott Laboratories, Inc.*, Case No. 3:05-CV-48, Notice of Removal (E.D. Ky. July 13, 2005); *Commonwealth of Kentucky v. Warrick Pharmaceuticals Corporation*, Case No. 05-CV-49, Notice of Removal (E.D. Ky. July 13, 2005); *State of New York v. Aventis*, Case No. 05-CV-0874, Notice of Removal (N.D.N.Y. July 13, 2005); *State of New York v. GlaxoSmithKline plc*, Case No. 05-CV-0874, Notice of Removal (N.D.N.Y. July 13, 2005); *State of New York v. Pharmacia Corp.*, Case No. 05-CV-0874, Notice of Removal (N.D.N.Y. July 13, 2005); *Commonwealth of Pennsylvania v. TAP Pharmaceutical Products, Inc.*, Case No. 05CV 3605, Notice of Removal (E.D. Pa. July 13, 2005); *State of Wisconsin v. Abbott Laboratories, Inc., et al.*, Case No. 05 C 0408 C, Notice of Removal (W.D. Wis. July 13, 2005); *State of Minnesota v. Pharmacia Corporation*, Case No. 05-CV-1394, Notice of Removal (D. Minn. July 13, 2005). On August 9, 2005, the JDML conditionally transferred all these actions to the Panel. As noted below, the Alabama, Pennsylvania and Wisconsin cases have subsequently been remanded to state courts by federal judges in those states.

transfer order, this action has been transferred to this Court. Most of the other actions are awaiting a final transfer ruling by the JPML.

In cases where objections were posed by plaintiffs, the JPML reaffirmed its original conclusion that:

transfer of these actions to that district for inclusion in the coordinated or consolidated pretrial proceedings occurring there will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation.

*See Exhibit A* at 1.

Among the AWP actions that were transferred to this Court were cases brought by the states of Minnesota, Montana, and Nevada. Those states alleged that the defendants violated state statutes and state common law by reporting inflated AWPs, and sued in their *parens patriae* capacity to recover such payments. All the cases were originally filed in state courts, but defendants removed them on the ground that some state-law AWP claims involved a substantial federal question. *State of Montana v. Abbott Labs.*, 266 F. Supp. 2d 250, 254-55 (D. Mass. 2003).

This Court, in ruling on motions to remand, found that state law claims to recover Medicare co-payments on behalf of a state's Medicare beneficiaries presented a federal question because they "require a determination of whether the AWPs reported" by [the defendant] comport with the meaning of AWP under the Medicare statute." *Id.* at 255. Specifically, the Court concluded that "proof of a discrepancy between the AWPs reported by" defendants and "the meaning of AWP under the Medicare statute" is "an essential element" of plaintiffs' state law claims. *Id.* The Court further observed that claims requiring "[t]he adjudication of . . . the term 'average wholesale price' in the

Medicare statute” implicate an important federal interest because they “could have broad implications for Medicare reimbursements and co-payments.”” *Id.* Despite these findings, this Court remanded Minnesota’s claims because the Medicare statute did not create a federal private cause of action. *Id.* at 256.

In June 2005, after the Court remanded Minnesota’s claims, the Supreme Court in *Grable* ruled that the absence of a federal private cause of action is not dispositive regarding whether a state law claim can give rise to federal jurisdiction. 125 S. Ct. at 2370. *Grable* thus altered the basis for this Court’s remand of the Minnesota action.

### **Argument**

#### **Defendants Meet the Legal Standards for Removal**

Removal to federal court is an important statutory right that Congress has expressly granted to defendants in specified classes of cases. Nevertheless, defendants readily acknowledge that, as movants, they have the burden of demonstrating federal jurisdiction. Such jurisdiction can be based on the four corners of plaintiffs’ complaint or looking beneath the complaint to divine the underlying nature of a claim. *Brawn v. Coleman*, 167 F. Supp. 2d 145, 148-49 (D.Mass. 2001).

Despite plaintiffs’ rhetoric about its right to choose its forum and “strict construction” of the removal statute, courts and commentators alike have recognized that “if the requirements of the removal statute are met, the right to remove is absolute.” 16 James W. Moore, et al., *Moore’s Federal Practice and Procedure* § 107.05 at 107-25 (3d ed. 2000). As demonstrated below, plaintiffs have not identified any ground to deny defendants their statutory right to a federal forum.

State law claims “arise under” federal laws “where the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9 (1983) (citation omitted). The fact that only “a subset” of the state law claims creates federal question jurisdiction is sufficient to confer federal jurisdiction over the entire action. *See Montana*, 266 F. Supp. 2d at 254 (“A state-court suit that includes at least one claim ‘arising under the Constitution, laws, or treaties of the United States’ can be removed to federal court.”) (quoting 28 U.S.C. § 1441) .

As noted above, this Court has already correctly ruled that “an essential element” of state law claims “is proof of a discrepancy between AWP’s reported by [the defendant] and the meaning of AWP under the Medicare statute” that “presents a federal question.” *Montana*, 266 F. Supp. 2d at 255. The Court found that state law claims necessarily required a finding that there was fraud under the Medicare program. Similarly, as shown below, Florida’s Medicaid claims present a substantial federal question. Florida’s state law claims necessarily require a judicial finding that there be fraud under the federal Medicaid laws.

Plaintiffs make the unsupported claim that removal of this action to federal court “deprives the state of any cause of action or any meaningful right of recovery on behalf of the Florida Medicaid Program . . . .” Motion for Remand at 11. Plaintiffs are wrong. This Court is fully capable of resolving all of Florida’s claims set forth in its Complaint, including the ability to provide full recovery in the event plaintiffs prevail in the litigation. Indeed, plaintiffs have made no claim or argument that resolution of their

claims will languish or be delayed if this case is heard in federal court. Other AWP cases are before this Court and there is nothing unique to plaintiffs' case that would raise even the slightest hint that plaintiffs would be "deprive[d] . . . [of] any meaningful right of recovery on behalf of the Florida Medicaid Program" in this Court. *Id.*

### **Plaintiffs' Medicaid Claims Present Substantial Federal Questions**

This Court is quite familiar with the structure and working of the Medicaid program. *See, e.g., Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314 (D. Mass. 2005); *In re Pharm. Indus. Average Wholesale Price*, 321 F. Supp. 2d 187 (D. Mass. 2004). However, neither case required this Court to determine whether an action based on Medicaid claims originally filed in a state court ultimately belongs in federal court. Thus, defendants will demonstrate below the substantial federal questions presented in this case by plaintiffs' Medicaid-based claims.

The Medicaid program is a cooperative venture between the federal and state governments, and is governed by the Social Security Act. *See* 42 U.S.C. §§ 1396-1396v; *Montana*, 266 F. Supp. 2d at 253; *Massachusetts*, 357 F. Supp. 2d at 318. The federal government sets standards for the Medicaid program, to be followed by each participating state, and provides funds to those states. *Massachusetts*, 357 F. Supp.2d at 318. Each participating state is required to develop a plan containing reasonable standards for eligibility and content of medical assistance within boundaries set by the federal Medicaid statute and regulations promulgated by the United States Department of Health and Human Services (HHS). *See generally Wisconsin Dept. of Health and Family Servs. v. Blumer*, 534 U.S. 473, 479 (2002). Indeed, the Florida statute that authorizes

the Florida Agency for Health Care Administration to administer Florida's Medicaid program provides that authority under *federal* law. *See* § 409.902, Florida Statutes.

HHS's Centers for Medicare & Medicaid Services (CMS ) is the "superintending federal agency" responsible for oversight of the Medicaid program. *Wisconsin Dept. of Health and Family Servs.*, 534 U.S. at 495-96. The federal government reimburses a state for a federally defined percentage of medical costs incurred by the state's Medicaid programs, if certain conditions are met, which include approval by the federal government of the state's Medicaid plan and compliance by the state with relevant federal requirements. 42 U.S.C. §§ 1396a(a), (b); 42 C.F.R. Part 447.

Plaintiffs' claims are based on state Medicaid costs incurred as a result of payment for covered outpatient prescription drugs. Medicaid payment for covered outpatient prescription drugs is established by federal statute. *See* 42 U.S.C. § 1396r-8.

An outpatient prescription drug is eligible for Medicaid coverage only if its manufacturer enters into an agreement (*i.e.*, a Medicaid Drug Rebate Agreement) with HHS to provide specified rebates to states on covered drugs used by state Medicaid recipients. 42 U.S.C. §§ 1396r-8(a), (b); *Pharmaceutical Research and Mfrs v. Thompson*, 259 F. Supp. 2d 39, 45 (D.D.C. 2003). Congress' purpose in requiring manufacturer rebates was to reduce the cost of the Medicaid program. *Pharmaceutical Research and Manufacturers of America*, 259 F. Supp. 2d at 56. Every rebate agreement requires compliance with 42 U.S.C. § 1396r-8, which imposes certain price reporting obligations on manufacturers (including defendants) and requires manufacturers to pay

rebates to states depending on state Medicaid recipients' utilization of covered drugs consistent with Medicaid program requirements. *Montana*, 266 F. Supp. 2d at 253-54.

As shown below, despite plaintiffs' attempt to disavow any claim for such rebates (Plaintiffs' Memo. at 4), these federally-mandated rebates will inevitably be an important element of what Florida will undoubtedly claim were improper amounts paid by defendants.

The Medicaid Drug Rebate Agreements are essentially federal contracts between the manufacturer and the United States that rely on definitions and terminology defined by federal law. In fact, the "General Provisions" of the rebate agreement explicitly require that the rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme. *See generally Montana*, 266 F. Supp. 2d. at 257-58. Under the terms of the Medicaid Drug Rebate Agreement, pharmaceutical companies' price reporting obligations are governed by federal law. *Id.* In fact, federal court jurisdiction is contemplated and established in the language of the Medicaid Drug Rebate Agreements.

States may also obtain authorization from CMS to enter into Supplemental Rebate Agreements with manufacturers of outpatient prescription drugs. Florida had a Supplemental Rebate Agreement approved by CMS in 2001. Florida is thus authorized to negotiate supplemental rebates from manufacturers in addition to Medicaid rebates that are already required under the Medicaid Drug Rebate Program. Florida must report any supplemental rebate payments to CMS. Florida must also remit the federal portion of any supplemental rebates collected under its Supplemental Rebate Agreement. Florida's

Supplemental Rebate Agreement is based on the federal Medicaid statute. 42 U.S.C. § 1396r-8(a). Therefore, Florida's pricing allegations, which are necessarily based in part on rebates paid under Florida's Supplemental Rebate Agreement, necessarily raise federal questions, because, among other things, they rely on federal pricing terminology and reimbursement methodology.

While neither the Medicaid Drug Rebate Agreements nor Supplemental Rebate Agreements define and/or establish a methodology for determining AWP or WAC, they are terms that are crucial to the State's case. Although not defined in law or regulations, the CMS, and many states, like Florida, have based reimbursement for certain drugs on terms such as AWP. *See* 42 U.S.C. §§ 1395l(a)(1)(S), 1395u(o)(1); *see also* Complaint, ¶¶ 18-20, 22; *Medicare Program, Payment Reform for Part B Drugs, Proposed Rule*, 68 Fed. Reg. 50,428, 50,429 (Aug. 20, 2003).

Moreover, Plaintiffs' Complaint relies on the meaning of the term "Federal Upper Limit." The FUL was established pursuant to federal law. 42 U.S.C. §§ 1396r-8(e), (f); 42 C.F.R. §§ 447.301-333. Plaintiffs have alleged that Federal Upper Limits "ensure [the Florida Medicaid agency] is a prudent purchaser of drugs." *See* Complaint ¶ 19.<sup>4</sup> It is thus wholly disingenuous for plaintiffs to now contend that if "Federal Upper Limits come into play at all in this litigation, it will be as a defense asserted by Defendants." Plaintiffs' Memo. at 5. Instead, to show any injury from defendants' alleged fraud,

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<sup>4</sup> The Complaint also references a defendant's "estimate of acquisition cost" and "usual and customary charge." Complaint ¶¶ 18-20. Those terms also appear in federal Medicaid regulations on drug reimbursement. 42 C.F.R. 447.331.

plaintiffs will have the burden to show that its reimbursements were made in accordance with existing laws and regulations, which would include compliance with any applicable Federal Upper Limits and other aspects of federal law.<sup>5</sup>

Although plaintiffs contend AWP, WAC and FUL have a specific meaning under the Florida Medicaid Program,<sup>6</sup> Medicaid drug payments have, from their inception, been inextricably linked to federal statutes and regulations that rely on AWP, WAC and FUL.<sup>7</sup>

The Florida Agency for Health Care Administration's (AHCA's) reimbursement procedures rely on federal terminology and determinations, including the FUL. *See* Complaint, ¶¶ 19-20. *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d at 320. AHCA must ensure that payments for certain multiple source drugs, *i.e.*, generics, do not exceed the FUL. 42 C.F.R. §§ 447.304, 447.332. Therefore, although AWP and WAC are not defined in the federal Medicaid statute or regulations, these terms do have a clear federally-defined role in Medicaid reimbursement throughout the country, including Florida.

Florida must comply with federal limits on, or exclusion from, coverage of certain prescription drugs in the Medicaid Drug Rebate Program. 42 U.S.C. §§ 1396r-8(d)-(e). These federal coverage and payment limitations also apply to Florida's Supplemental Rebate Agreement. *See* 42 U.S.C. § 1396r-8(d); *see also generally Multicare Med. Ctr.*

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<sup>5</sup> HHS implemented drug reimbursement rules setting an upper payment limit for Medicaid and other programs. The rules set limits on payments for drugs supplied under Medicaid and other programs. 42 C.F.R. Part 447.

<sup>6</sup> Plaintiffs' Memo at 5.

<sup>7</sup> 42 U.S.C. §§ 1396r-8(e), (f); 42 C.F.R. Part 447.

*v. Washington*, 768 F. Supp. 1349, 1357 (W.D. Wash. 1991) (citing *Amisub, (PSL), Inc. v. Colorado Dept. of Social Services*, 879 F.2d 789, 794 (10th Cir.1989)). Consequently, compliance with federal law is the *sine qua non* under which state Medicaid programs are bound.<sup>8</sup>

Medicaid Drug Rebate Agreements establish manufacturer reporting requirements. Manufacturers of Medicaid-covered outpatient prescription drugs must report certain pricing information to CMS quarterly for covered outpatient prescription drugs. 42 U.S.C. § 1396r-8(b), (k)(1); 42 C.F.R. § 447.534 (2004). CMS uses this information along with utilization data reported by states to determine the Unit Rebate Amount (URA). 42 U.S.C. § 1396r-8(c). The manufacturer pays rebates to Florida based on the utilization information reported to the federal government, after applying the federally-determined URA. Without federal rules and guidelines, including compliance with federal Medicaid reporting requirements, Florida would be unable to obtain rebates for covered outpatient drugs from manufacturers.

Indeed, a determination that a rebate paid to AHCA was inappropriate necessarily affects the Federal Financial Participation Percentage (FFP) paid by HHS. A finding that Florida exceeded the FUL affects the FFP. 42 C.F.R. § 447.304(c); *Pharmaceutical Society of New York, Inc. v. New York Dept. of Social Services*, 50 F.3d 1168, 1173 (2<sup>nd</sup> Cir. 1995).

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<sup>8</sup> In fact, the United States Supreme Court has just granted certiorari in a case that involves whether the *Federal* Medicaid laws limit the amount that state Medicaid plans may recoup. *Ahlborn v. Arkansas Dept. of Human Services*, 397 F.3d 620 (8<sup>th</sup> Cir. 2005), *cert. granted*, 74 U.S.L.W. 3170 (U.S. Sept. 27, 2005) (No. 04-1506).

Plaintiffs seek damages which consist of the alleged difference between what the Florida Medicaid Program should have paid in pharmacy claims and what was in fact paid. *See* Complaint, ¶ 93. To determine any such damages to Florida, there must be a set-off for any amounts that the federal government paid Florida. That calculation would affect the FFP. 42 U.S.C. §§ 1396b(a)-(d), (f), (i)(10). Specifically, the drug rebate provisions of the federal Medicaid statute explicitly requires Florida to offset rebates received from manufacturers under Medicaid Drug Rebate Agreements or Supplemental Rebate Agreements to reduce the federal share paid by HHS under section 1903 of the Social Security Act. 42 U.S.C. § 1396r-8(b)(1)(B). Consequently, any determination that manufacturer rebates to Florida should be increased or decreased will affect the federal share paid by HHS under federal law.

This Court has ruled that “[t]he adjudication of whether the term ‘average wholesale price’ in the Medicare statute embraces a ‘spread’ could have broad implications for Medicare reimbursements and co-payments.” *Montana*, 266 F. Supp. 2d at 255. A ruling that defendants fraudulently inflated prices for covered drugs in the Medicaid program would necessarily imply that defendants also inflated the federal government’s share because the Medicaid program and the federal shares are both based on reported AWP. Such a ruling against the numerous defendants in this case would implicate hundreds of millions of dollars of federal funds and presents a paramount federal interest.

Plaintiffs assert that there are no claims pertaining to Medicaid rebate fraud in this case. Plaintiffs’ Memo. at 4. However, there is no doubt that the amounts paid by drug

companies under their Medicaid Drug Rebate agreements and/or Supplemental Rebate Agreements will directly impact Florida's pricing claims. As such, plaintiffs' allegations require the interpretation of contractual obligations to the United States. Inevitably that interpretation will depend on the meaning of terms and requirements that are hardly unique to Florida, which is another reason why the case properly belongs in federal court. *Grable*, 125 S.Ct. at 2367; *Montana*, 266 F. Supp. 2d at 258. "Where the resolution of a federal issue in a state-law cause of action could, because of different approaches and inconsistency, undermine the stability and efficiency of a federal statutory regime, the need for uniformity becomes a substantial federal interest, justifying the exercise of jurisdiction by federal courts." *Ormet Corp. v. Ohio Power Co.*, 98 F.3d 799, 807 (4th Cir. 1996) (citation omitted).<sup>9</sup>

Inconsistent decisions on the meaning of AWP, WAC and FUL would sow confusion in the administration of the federally supported Medicaid programs in all states. *See In re: Zyprexa Prod. Liab. Litig.*, 375 F. Supp. 2d 170, 172-73 (E.D.N.Y. 2005) (recognizing that "the substantial federal funding provisions involved [in Medicaid programs] and the allegations about the violation of federal law" warrant federal jurisdiction); *Municipality of San Juan v. Corporacion Para El Fomento Economico De Law Ciudad Capital*, 415 F.3d 145, 148 n.6 (1st Cir. 2005) (finding federal jurisdiction

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<sup>9</sup> Defendants acknowledge that this Court concluded that state courts are competent to interpret terms in federal statutes relating to drug pricing. *In re Pharma. Indus. Average Wholesale Price*, 321 F. Supp. 2d at 200. However, this conclusion does not alter the principles we have set forth in this Memorandum showing that this case belongs in federal court.

proper when state law claims that necessarily implicate a federal issue present a sufficiently important federal interest to warrant federal jurisdiction).

**Recent Decisions by Other Courts Are Neither Binding Nor Persuasive**

Although plaintiffs trumpet the recent remand decisions by Alabama and Pennsylvania federal courts (which were exhibits to Plaintiffs' Memo.), these decisions fly in the face of a prior ruling by this Court that the meaning of AWP was an "essential element" of claims brought by Minnesota to recover Medicare payments based on AWP because such claims required "proof of a discrepancy between AWP's report by [the defendants] and the meaning of AWP under the Medicare statute." *Montana*, 266 F. Supp. 2d at 255.

The Alabama ruling was in the form of a two-page order that concluded, without analysis, that the claims presented in the cases did not "necessarily raise a stated federal issue." Order at 1. The Pennsylvania Court ruled that plaintiff's claims did not present a substantial issue of federal law. That Court found that the term AWP is not "actually disputed." Penn. Slip. Op. at 12. In contrast, defendants anticipate that the meaning of this term will be hotly disputed and will inevitably be examined pursuant to federal standards.<sup>10</sup>

The Pennsylvania Court also found that the Medicare system would be unaffected by a state court adjudication of that case because AWP is no longer the Medicare

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<sup>10</sup> That Court also ruled that Pennsylvania could prevail even without needing to ascribe any meaning to AWP. *Id.* This finding directly conflicts with this Court's ruling in *Montana*.

reimbursement standard. *Id.* at 13. While it is true that Medicare reimbursement now relies in large part on reimbursement based on average sales price (ASP) for covered drugs, some Medicare drug reimbursement is still based on a percentage of AWP. Moreover, the federal government and Medicare program are certainly reliant on AWP for all drugs for which AWP was reported prior to the enactment of the Medicare Prescription Drug, Modernization and Improvement Act of 2003, to the extent there are questions about past pricing practices. Indeed, it is “past” pricing practices that are at the heart of Florida’s case.

Finally, that court further found that the Medicare statute authorizes states to supervise conduct that adversely affects Medicare beneficiaries without federal oversight and, as a result, Pennsylvania’s claims do not implicate a substantial federal interest. *Id.* at 14, n.6. The Court incorrectly confused a state’s right to supervise the conduct of drug companies with the substantial federal interests implicated by a state’s Medicaid claims.

After Florida filed its Memorandum, a Judge in Wisconsin remanded a drug pricing case to state court. *Wisconsin v. Abbott Labs.*, No. 05-C-408-C (W.D. Wis. Sept. 29, 2005) (Slip Op.) (attached as Exhibit B). That Court found that plaintiff’s claims did present a substantial and disputed question of federal law with regard to recoupment of alleged overpayments under the federal Medicaid and Medicare laws. *Id.* at 16. Nevertheless, Judge Crabb incorrectly decided that remand was proper because allowing the case to proceed in federal court could “work a significant disruption in the division of labor between federal and state courts.” *Id.* at 18.

This Court should not be concerned about such disruption. It has spent over three years wrestling with the factual and legal intricacies of the AWP litigation and the meaning of AWP and multiple state law actions are already before it. Moreover, it has at least two other cases where drug companies' pricing practices are alleged to have violated the Medicaid laws.

By way of comparison, the Alabama, Pennsylvania and Wisconsin cases were on their district court's dockets for months when they reached conclusions that directly conflicted with those of this Court. The MDL process is designed to avoid just such inconsistent district court rulings. *See In re Aimster Copyright Litig.*, 177 F. Supp. 2d 1380, 1382 (J. M. P. L. 2001); *In re Auto Refinishing Paint Antitrust Litig.*, 177 F. Supp. 2d 1378, 1379 (J. M. P. L. 2001).

### **Conclusion**

Plaintiffs' Motion For Remand should be denied.

Respectfully submitted,

October 14, 2005

s/ \_\_\_\_\_  
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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been sent  
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